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| APPLICATION NO.                            | FILING DATE                     | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|---------------------------------|----------------------|---------------------|------------------|
| 10/584,867                                 | 06/29/2006                      | Michael Schneider    | 0262-061920         | 7715             |
|  | 7590 12/24/200<br>AW FIRM, P.C. | EXAMINER             |                     |                  |
| 700 KOPPERS                                | BUILDING                        |                      | TOUSSAINT, DALILA   |                  |
| 436 SEVENTH AVENUE<br>PITTSBURGH, PA 15219 |                                 |                      | ART UNIT            | PAPER NUMBER     |
|  |                                 |                      | 1794                |                  |
|  |                                 |                      |                     |                  |
|  |                                 |                      | MAIL DATE           | DELIVERY MODE    |
|  |                                 |                      | 12/24/2008          | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|  | Application No.   | Applicant(s)             |  |  |  |  |
|--|---|--------------------------|--|--|--|--|
|  | 10/584,867  | SCHNEIDER ET AL.         |  |  |  |  |
| Office Action Summary  | Examiner  | Art Unit                 |  |  |  |  |
|  | DALILA TOUSSAINT  | 1794                     |  |  |  |  |
| The MAILING DATE of this communication app<br>Period for Reply   | ears on the cover sheet with the c                            | orrespondence address    |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |                          |  |  |  |  |
| Status   |   |                          |  |  |  |  |
| 1) Responsive to communication(s) filed on   |   |                          |  |  |  |  |
|  | -·<br>action is non-final.                                    |                          |  |  |  |  |
| <i>;</i> —   | , <del></del>   |                          |  |  |  |  |
| closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  |   |                          |  |  |  |  |
|  |   |                          |  |  |  |  |
| Disposition of Claims  |   |                          |  |  |  |  |
| 4)⊠ Claim(s) <u>21-30</u> is/are pending in the application.   |   |                          |  |  |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.   |   |                          |  |  |  |  |
| 5) Claim(s) is/are allowed.  |   |                          |  |  |  |  |
| 6)⊠ Claim(s) <u>21-30</u> is/are rejected.   |   |                          |  |  |  |  |
| 7) Claim(s) is/are objected to.  |   |                          |  |  |  |  |
| · · · · · · · · · · · · · · · · · · ·  |   |                          |  |  |  |  |
|  | ·   |                          |  |  |  |  |
| Application Papers   |   |                          |  |  |  |  |
| 9)☐ The specification is objected to by the Examiner.  |   |                          |  |  |  |  |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.  |   |                          |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |   |                          |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).   |   |                          |  |  |  |  |
| 11)☐ The oath or declaration is objected to by the Exa   | aminer. Note the attached Office                              | Action or form PTO-152.  |  |  |  |  |
| Priority under 35 U.S.C. § 119   |   |                          |  |  |  |  |
| <u> </u>   | priority under 35 LLS C & 119(a)                              | h-(d) or (f)             |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:   |   |                          |  |  |  |  |
| 1. ☐ Certified copies of the priority documents  | s have been received  |                          |  |  |  |  |
| 2. Certified copies of the priority documents  |   | on No                    |  |  |  |  |
|  | • •   |                          |  |  |  |  |
| 3. Copies of the certified copies of the prior   | •   | d in this National Stage |  |  |  |  |
|  | application from the International Bureau (PCT Rule 17.2(a)). |                          |  |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.   |   |                          |  |  |  |  |
|  |   |                          |  |  |  |  |
|  |   |                          |  |  |  |  |
| Attachment(s)  |   |                          |  |  |  |  |
| 1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)  |   |                          |  |  |  |  |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  Paper No(s)/Mail Date  Notice of Information Disclosure Statement(s) (PTO/SB/08)  Notice of Information Patent Application  |   |                          |  |  |  |  |
| B) ☑ Information Disclosure Statement(s) (PTO/SB/08) 5) ☑ Notice of Informal Patent Application Paper No(s)/Mail Date <i>05/18/07</i> . 6) ☑ Other:  |   |                          |  |  |  |  |
| 1 apor 110(0), main batto <u>00/10/07.</u>   |   |                          |  |  |  |  |

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## **DETAILED ACTION**

## Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 2. The term "up to about" in claim 22 is a relative term which renders the claim indefinite. The term "up to about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.
- 3. Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. A product-by-process claim, is a product claim that defines the claimed product in terms of the process by which it is made.

## Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 5. Claims 21, and 23-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Sawatzki et al. WIPO publication WO 9933355.

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a. Referring to claims 21, and 23-30, Sawatzki et al. discloses a fat blend made of lecithin-based fat, see abstract shown below, wherein the lecithin based fat comes from egg yolk and/or other fish, and marine mammals (page 4, ¶ 5, line 2-7).

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The invention relates to an oil, fat and/or lecithin-based fat blend containing polyunsaturated fatty acids. The inventive fat blend is characterized in that the fatty acids gamma-linolenic, stearidonic acid and eicosapentaenoic together make up 10 to 500 mg/g total fatty acids. The gamma-linolenic and eicosapentaenoic acids each represent 20 to 50 wt. % and the stearidonic acid represents 15 to 50 wt. % of the sum of these three fatty acids. The inventive fat blend can be incorporated into a dietetic or a pharmaceutical product, especially a dietetic food, and can be used especially for administering to patients suffering from chronic/inflammatory diseases, disorders of the lipid metabolism, a weakened immune function and/or a restricted lipolytic capacity of the gastrointestinal tract.

Also, Sawatzki et al. disclose producing the fat blend by chromatographic separation of animal fats and oils to obtain polyunsaturated fatty acid that have long carbon chains (C20 and C22; page 1, ¶ 4, line 1-5) on page 4, ¶ 4, line 6-11.

In addition, for example GLA- and SA-rich concentrates produced in chemical or enzymatic ways and also those obtained from the said sources by chromatographic separation can be used. As animal fats and oils, for example, egg oils, fish oils and oils from marine mammals, and also for example eicosapentaenoic acid-rich or stearidonic acid-rich concentrates produced in chemical or enzymatic ways and also those

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obtained from these raw materials by chromatographic separation can be used.

The fat blend according to the reference embodiment can be in any desired nature i.e. a fat emulsion, a liquid food, a reconstituted powder food or a reconstitutable powder food (page 5, ¶ 4, line 1-7). Also, "the dietetic foodstuffs according to the invention contain not only a fat mixture or a fat blend of the type described above, but can also contain other products, for example protein of animal and/or plant origin, e.g. milk, whey, peas, wheat and/or soya, in the form of complex and/or hydrolysed protein with or without addition of free amino acids and/or dipeptides as well as carbohydrates (maltodextrins), vitamins, roughage, minerals, trace elements, choline, taurine, carnitine, inositol and nucleotides in different quantity proportions and optionally water. These further components can be mixed with the fat blend as desired."(page 6, ¶ 6, line 1-7)

Note that the reference specification discloses (see above) that the fat blend can have any desired amount of carbohydrates; therefore the remaining limitations are inherent.

b. Referring to claim 22, Sawatzki et al. disclose the fat blend in the form of phospholipids can comprises up to 120 mg/g of the total fatty acid (12%) (page 4, ¶ 2, line 3-4). "Further, medium-chain triglycerides (MCT) can be used in the claimed fat blend. The expressions "fats, oils and lecithins" used here mean technological starting materials. On the other hand, terms such as phospholipids and triglycerides refer to the chemical species. Thus it is quite possible for an oil

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also to contain phospholipids (often also described as lecithins) and for a lecithin also to contain triglycerides" (page 4, ¶ 5, line 6-11).

- 6. Claims 21-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Akimoto et al. EPO publication EP 0775449 A1.
  - c. Referring to claim 21 and 24, Akimoto et al. disclose a solid fat product based on fowl eggs having high content of unsaturated fatty acids (abstract), having preferably at least 20 carbon atoms (page 4, line 20) wherein the desirable oil containing highly unsaturated fatty acid contains at least 20% arachidonic acid with respect to total fatty acid (page 4, line 31-33).
  - d. Referring to claim 22 and 25, Akimoto et al. disclose within its embodiment phospholipids obtained from fowl eggs (page 3, line 38-46). However, Akimoto et al. fails to disclose the amount within it embodiment. As Akimoto et al. uses like materials in a like manner as claimed, it would therefore be expected that the contents of phospholipids will have the same characteristics claimed, particularly up to 35 wt.% of the oil component.
  - e. Referring to claim 23 and 28, Akimoto et al. disclose powdered microbial cells containing 60% oil having a high content of  $\omega$ 6 highly unsaturated fatty acids (page 6, line 49-50).
  - f. Referring to claim 26 and 27, Akimoto et al. teaches:

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(1) The solid fat product according to claim 21, wherein the solid fat product has a carbohydrate content of at most 5 wt.% based on the fat product dry matter (page 6, line 47).

- g. Referring to claim 29, Akimoto et al. teaches;
  - (2) The solid fat product according to claim 21, wherein at least part of the fat or oil component originates from a fat or oil component selected from the group consisting of an animal fat (abstract and page 3, line 59).
- h. Referring to claim 30, Akimoto et al. disclose the instant claim in page 6, line 5-16, as shown below:

The egg yolk lipid of the present invention thus obtained is richer in arachidonic acid than conventional eggs. More specifically, this egg yolk lipid contains at least 2%, preferably at least 2.7%, and more preferably at least 3% arachidonic acid with respect to the total fatty acids contained in the egg yolk. In addition, in the present invention, fatty acid analysis of the resulting lipid having a high content of arachidonic acid and docosahexaenoic acid indicates a ratio of 1 to 12 parts by weight of docosahexaenoic acid to 1 to 12 parts by weight of arachidonic acid. Moreover, said egg yolk lipid is characterized by demonstrating a ratio of at least 5 parts by weight of arachidonic acid to 1 part by weight of eicosapentaenoic acid.

Therefore, the lipid of the present invention having a high content of arachidonic acid and optionally docosahexaenoic acid extracted from domestic fowl eggs, and particularly the egg yolks, obtained by feeding egg-laying domestic fowls with o)6 highly unsaturated fatty acid and optionally o)3 highly unsaturated fatty acid has a low ratio of eicosahexaenoic acid with respect to total fatty acids in the egg yolk even in the case the above-mentioned domestic fowls are raised using fish oil for the o)3 highly unsaturated fatty acid.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DALILA TOUSSAINT whose telephone number is

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(571)270-7088. The examiner can normally be reached on Monday - Friday, 8:00 a.m. - 5:00 p.m., EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carol Chaney can be reached on (571)272-1284. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. SAYALA/ Primary Examiner, Art Unit 1794

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